FRONTIERS
THE HEARTLAND INSTITUTE FOR
CLINICAL AND TRANSLATIONAL RESEARCH

Pilot and Collaborative Studies Funding Program (FY 2015)

REQUEST FOR PROPOSALS

FIFTH FUNDING ROUND

(PLEASE READ VERY CAREFULLY AND TAKE NOTE OF DEADLINES)

Announcement Date: August 15, 2014
Letter of Intent Due Date: September 15, 2014 (5:00 PM CST)
Application Due Date: October 31, 2014 (5:00 PM CST)
Announcement of Awards: March, 2015

***Frontiers*: The Heartland Institute for Clinical and Translational Research** is pleased to announce the availability of grant funds for pilot translational and clinical research conducted by investigators affiliated with institutions comprising the Heartland Institute for Clinical and Translational Research. The Pilot and Collaborative Studies Funding Program is funded through an NIH-supported Clinical and Translational Science Award (CTSA) made to the University of Kansas Medical Center. The Program is administered through the KUMC Research Institute, Inc. Please see our website (FrontiersResearch.org) for information about *Frontiers*.

The mission of the *Frontiers* Pilot and Collaborative Studies Funding Program is to provide both junior and established investigators research funds to support clinical or translational pilot/feasibility studies and novel methods development in high-priority research areas that will lead to the submission of peer-reviewed grants. At least ten (10) awards of $20,000 each will be made in this funding cycle, depending on availability of funds. These awards support both junior (up to and including Assistant Professor level appointment) and more established faculty (Associate Professor; Professor level appointments).

Scope of the Program

The type of research supported by this program includes:

- Preclinical studies that are directly relevant to human health and use human cells or other human biological materials, with the endpoint of identifying new therapies or biomarkers.
- Early bench to bedside research leading up to and including first-in-human and/or clinical proof of concept trials evaluating new drug treatments, medical devices and diagnostics
- Community-based clinical research studies using human subjects, families, and/or communities for testing new treatments or interventions, assessing new health

outcomes, etc.
- Studies of effectiveness and/or implementation and/or dissemination of clinical research findings into practice.

For NIH definitions of clinical research, refer to the appendix at the end of this RFP. *In vivo* preclinical studies and *ex vivo* studies using animal models and tissues will be considered only if results lead directly to clinical research. Specific questions regarding the scope of this program can be directed to Peter Smith, Ph.D., Program Director (psmith@kumc.edu).

SPECIAL NOTE: All awarded funds must be expended by February 28, 2016, although the actual research may continue until the final report is due. Projects already initiated, including those with other support from internal, foundation, or similar sources, and for which the funds requested in this application could be scientifically justified as additional, non-duplicative support are eligible and encouraged.

Eligibility Requirements

- All faculty members/investigators of institutions/organizations affiliated with *Frontiers*: The Heartland Institute of Clinical and Translational Research are eligible to apply.
- Applicants are eligible if they are on a faculty track or in a position that permits them to apply for extramural grants from their institution.
- Applicants who have not progressed past the Assistant Professor level at the time of proposal submission will be considered junior investigators.
- Adjunct faculty with primary appointments in a non-*Frontiers* affiliate institution/organization may be co-investigators, but may not submit a proposal as the Principal Investigator.
- Principal Investigator(s), Co-Investigator(s) and all listed personnel must be legal residents of the U.S. or otherwise eligible to receive federal funding. Special consideration will be given to proposals that promote collaboration among Frontiers investigators from different disciplines and/or from different institutions, and proposals that provide home departmental / institutional / organizational matching or contributed funds.
- Only one proposal will be accepted per Principal Investigator (PI) (whether as a single PI or as a named multiple PI) in this funding cycle, although a PI on one proposal can be listed as a collaborator on other submitted proposals.

Required Submission Items (in the following order)

The proposal is to follow the basic NIH format and includes the following PHS-398 (Department of Health and Human Services, Public Health Services) grant application form:

1. **Face Page** (Page 1): Contains project title and information regarding Principal investigator(s)/Program Director. Be sure to include if you are applying under the "Junior Faculty" designation.
2. **Project Description** relating to broad, long-term objectives and specific aims, performance sites, key personnel and other significant contributors. The project description must also address how the proposed work will lead to future extramural funding. (Page 2)
3. Research Grant **Table of Contents** (Page 3)

4. **Detailed Budget** (Page 4):
   - Budgets requests should not exceed $20,000 (no indirect dollars are awarded).
   - Faculty and research staff salaries are permitted. However, no more than 10% of the PI's salary should be allocated to the budget, and if grant funds are used to provide release time, that time **must** be matched by departmental release time—e.g., if 10% of PI's salary is charged to the grant, another 10% must by donated for a total of 20% effort dedicated to the proposed project. **NOTE:** The actual monetary value of donated effort must be documented in a letter from the investigator's departmental chair which should also confirm that the committed research time is protected.
   - Any other cost share funds available to the project should be identified and supported by a letter from the funding source. Travel is not permitted unless clearly needed to collect data, and specifically documented.
   - Core Support: Support from *Frontiers* cores (see below) can be provided to investigators in support of their proposals, and investigators are encouraged to use these resources as appropriate for their proposed studies. Use of specific *Frontiers* cores is not required. **NOTE**: Any costs that would be incurred by the use of specific cores needed for the project must be included in the proposal budget and must have sign-off or a letter from the respective core director. See the "Research Resources" tab in the *Frontiers* website (FrontiersResearch.org) for additional information. Consultation/ services will be given on a "first come-first serve" basis. During the time of that consultation, specific charges for services and other support that will be included in the proposal budget should be obtained. It is highly recommended that advice be sought prior to the LOI deadline (September 15, 2014, 5:00 PM CST). The absolute deadline for consultation for this funding cycle is October 30, 2014, 5:00 PM CST.
     - *Regulatory Knowledge and Support Program*: This program assists investigators with resources to navigate and meet all regulatory and administrative requirements for clinical and translational research.
     - *Community Partnerships for Health (CPH)*: The CPH program connects investigators with Kansas and Kansas City-metropolitan area communities for research projects that will be conducted in and with communities to improve the health of the community. Services for investigators include training and partnership-building for respectful access to and working with diverse communities, and assistance with obtaining patients or lay persons for focus groups if needed.
     - *Biostatistics*: Biostatisticians skilled in a full range of statistical and methodological approaches are available to consult with investigators and provide support for research method design, statistical support and statistical analysis. As a *Frontiers* project, initial consultation and planning regarding biostatistical analysis for the project is available through the KUMC Department of Biostatistics at no charge.
     - *Biomedical Informatics*: This program provides informatics resources to support investigator research, including online survey tools and access to state and other data resources for health research; staff can help investigators select the most appropriate database for their projects.
     - *Clinical and Translational Science Unit (CTSU)*: The CTSU includes a

wide range of resources, from a fully equipped Exercise Physiology lab to a state-of-the-art Metabolic Kitchen. With examination, infusion and observation rooms, experienced research nurses and medical staff, the CTSU can monitor patients on clinical trials in a safe and controlled environment. As a *Frontiers* project, basic nursing costs and room charges for use of the CTSU will be waived, but other needs for more complex services of the CTSU will need to be included in the proposal budget. Contact Andra Lahner (alahner@kumc.edu; 913-588-0980) to get appropriate charges for these needs and information on what other CTSU resources may be available with waived charges.

- *Translational Technologies Resource Center (TTRC)*: The TTRC provides investigators with access to advanced *in vivo*, and cell and tissue imaging resources, a genomics and proteomics lab, and tissue repositories. The TTRC also manages the Pharmacokinetic and Pharmacodynamic Program within *Frontiers* to support pre-clinical, clinical and post-marketing phases of the drug development process.
- *Institute for Advancing Medical Innovation (IAMI)*: The IAMI assists investigators with advancing new drugs, drug products and drug delivery platform technologies through the approval process. The IAMI also provides proof-of-concept awards and an Office of Project and Portfolio Management to identify projects, create project teams and set timelines.
- *Personalized Medicine and Outcomes Center (PMOC)*: The PMOC focuses primarily on supporting investigators with research that addresses translating scientific discoveries into practical applications for patients. This includes assisting with analysis of large databases; quality assessment and quality improvement analysis; health and healthcare economics, health status and decision analysis; and survey design and qualitative research support.
- *Ethics Program*: The Ethics Program consults with investigators regarding the ethical implications of their research at every stage from design to reporting of results. The program also provides training, facilitates community collaboration and aims to stimulate the field of research ethics.

5. **NIH Biographical Sketch**: For all investigators, use the current NIH format that includes an initial project-specific paragraph about each investigator's role. See: (http://grants.nih.gov/grants/funding/phs398/biosketchsample.pdf). Also include information about past grant support and effort allocation on pending applications and current research projects.
6. **Research Plan**: To be typed in Microsoft WORD using Arial 11 font size and at least 0.5 inch margins. The research plan may not exceed five (5) pages (excluding references) and must include the following:
   - Specific Aims
   - Research Strategy
     - Significance
     - Innovation
     - Approach
   - Identify which data or other product from this pilot study will be included in a future proposal for funding from an extra-mural agency, organization or foundation (e.g.,

NIH, American Heart Association).
- The names of potential funding sources for which this pilot research will be used to support a proposal for future research, the probability of such funding and a planned date of submission.
- References (not included in the 5 page limit)

7. **Appendix**: Include measurement instruments and similar items. The Appendix **may not** be used to provide additional data or information that should be part of the 5 page proposal.
8. **Letter(s) of Collaboration**: From the collaborator(s), if any, explaining their role(s) in the proposed research and confirming their agreement to participate in the project.
9. **Letter(s) from the Respective Chair(s) or Institutional/Organizational Official**: Indicating support for time allocation of the investigator(s) to do the research and any other contribution to the project. If applicable, documentation indicating any commitment of matching or contributed funds to support the research project. Other than matching time/effort if PI salary is requested, departmental or other contributed funds are highly encouraged, but not required.
10. **Status of IRB or IACUC submission**: Please provide updated documentation on where the proposal is in theapproval process. If approval has been granted, include confirming documentation. If approval is not complete, indicate whether or not it is currently in process and if so submit documentation and a draft of the IRB application.

Prioritization and Review Criteria

The Review Committee will consider the experience level of the applicant (junior versus more senior and experienced) when evaluating proposals. Five (5) awards will be reserved for meritorious applications from junior faculty. The Review Committee also strongly recommends that, if possible, junior applicants solicit scientific consultation or review from a mentor to ensure that the applicant has met all of the criteria and requirements in this RFP.

The review criteria for this RFP are essentially the same as those used by Federal agencies, such as NIH, NSF and the Department of Education:

- Scientific, technical, or clinical **significance** and originality (**innovation**) of proposed research.
- Appropriateness and adequacy of the research design and methodology proposed to conduct the research (**approach**).
- Qualifications and research experience of the Principal Investigator(s) and staff, particularly, but not exclusively, in the area of the proposed research (**investigator**).
- Availability of the resources (**environment**) necessary to perform the research (projects that demonstrate matching or contributed departmental/ center or institute/ institutional/organizational funds are desirable). Reviewers also will take into account how applicants use *Frontiers* core resources, if appropriate. Using Frontiers core resources is not required.
- Appropriateness of the proposed budget and timeline in relation to the proposed research
- Provisions for the protection of human or animal subjects
- Compliance with the Conflict of Interest Policy
- Potential for future external funding possibilities (**#1 criterion for funding decisions among meritorious proposals from this peer review**)

Peer Review

The Review Committee will be composed of investigators from *Frontiers* institutions who will conduct peer-review of these proposals. Applicants may submit up to three (3) names of persons they wish to have excluded from the review process. This is allowed to avoid selection of someone with whom the applicant does not wish to share the proposal.

The *Frontiers* Pilot Studies Program Steering Committee (not the review committee) will make the final determination of funding based on the reviews/critiques submitted by the *Frontiers* peer-reviewers, potential for future funding, and priorities with respect to available resources.

Key Deadline Dates and Details

Announcement Date: August 15, 2014

Intent to Submit Application (Letter of Intent; LOI): by September 15, 2014 (5:00 PM CST). **NO EXTENSIONS TO THIS DEADLINE**

- Access REDCap (https://redcap.kumc.edu/surveys/?s=9tqgARtUmQ). This will get you to the REDCap LOI submission form. Please read the letter accompanying the LOI Application, fill out all of the required data blocks and then upload your LOI (MS Word, MS Excel; pdf). Make sure that your LOI briefly (200 words or less) but adequately describes the research project to facilitate identifying expertise needed for the review of your application. Please also make sure that the keywords that you list adequately summarize the work proposed.
- Please contact Kelly Robertson at the KUMC Research Institute if you have any questions or problems (krobertson@kumc.edu).

Submission of Application: by October 31, 2014 (5:00 PM CST). **NO EXTENSIONS TO THIS DEADLINE**

- Once the LOI has been submitted through REDCap, an email will be sent to the email address listed in the LOI application. The REDCap link to the full application will be supplied in this email.
- Applicants should use this link to upload the requested information and the full application in the same manner as described above.

- **PLEASE NOTE:** KUMC faculty also may have their proposal considered for funding through the KUMC Research Institute Clinical Pilot Research Program (if eligible), or the KUMC Research Institute Lied Basic Science Grant Program (if eligible) by indicating the appropriate option(s) on the REDCap submission forms for both the LOI and the full application. If these options are chosen, please recognize that the eligibility requirements, rules and required submission items could be different as stated in the respective RFPs, and must be addressed in the application.

Announcement of Awards: *March, 2015.*
NOTE: As of this announcement date, expenditure of *Frontiers* funds will not be permitted until March 1, 2015 or until the official CTSA Notice of Grant Award is received. If matching funds are available from other funding programs, those funds could be used prior to receipt of the CTSA NOGA, dependent on when they are made available.

Progress and Final Reports: Specific information on the content for the progress reports, as well as any other requirements, will be provided to the awardees shortly after the award is made. Content for final reports also will be provided. A formal report is due each November 15; however, awardees will be contacted 5-6 months after funding starts for a status check regarding progress. Please note that awardees will be required to present their findings at an annual Frontiers Symposium or other event. Awardees will be notified of the venue for each year when this is determined.

November 15, 2015: An initial progress report is necessary by this deadline for meeting NIH reporting deadlines.

November 15, 2016: Either a final or interim report is due by this date.

November 15, 2017: All final reports are due by this date. No extensions will be granted.

For questions or additional information, please contact the following individuals:

Kelly Robertson 913-588-5436; krobertson@kumc.edu
Peter Smith, Ph.D. 913-588-5970; psmith@kumc.edu

APPENDIX

The NIH definition of clinical research is:

- **Patient-oriented research:** This type of research involves a particular person or group of people or uses materials from humans. This research can include:
  - Studies of mechanisms of human disease
  - Studies of therapies or interventions for disease
  - *Clinical trials* (see About clinical trials for more details): [http://www.nichd.nih.gov/health/clinicalresearch/aboutclinicaltrials.cfm]
  - Studies to develop new technology related to disease
- **Epidemiological and behavioral studies:** These types of studies examine the distribution of disease, the factors that affect health, and how people make health-related decisions.
- **Outcomes and health services research:** These studies seek to identify the most effective and most efficient interventions, treatments, and services.

See: http://www.nichd.nih.gov/health/clinicalresearch/ for more information on NIH definition of clinical research and clinical trials.